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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,485	07/13/2001	Avi Ashkenazi	10466/44	8938

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/904,485	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: _____.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud

Applicant traverse the rejection of the claims with regard to the MLR/MLC assay. Applicant asserts that the MLR assay is well-established. Applicant also asserts that the assay is useful for assessing the immune response of an individual to allogens. These facts are not disputed by the Examiner. However, this information still doesn't lend utility/use to the instant polypeptide for the reasons of record.

Applicant addresses the Kahan reference, however, this interpretation is rather literal. Kahan speaks specifically to "immunosuppression", but the ability of in vitro assays to predict or correlate with immunosuppression could also be applied to immunostimulation. There is no indication in the art that any in vitro immune assay predicts or correlates with immunostimulation as well. Kahan speaks to immunosuppression because most researchers and physicians are most concerned with immunosuppression. However, if one of ordinary skill in the art concluded that an in vitro immune assay is not predictive or correlative with immunosuppression, they are also likely to conclude that the same asssay is not predictive or correlative with immunostimulation, absent evidence to the contrary.

Applicant further argues that inhibitors of MLR have utility in suppressing the immune response in graft transplantation. However, the asserted utility of the claimed invention is a stimulatory molecule. The only indication of what the claimed invention is to be useful for is for general increase of natural defenses, which is not a substantial utility at the time the instant application was filed. There is no teaching in the art or in the instant specification which would make this asserted utility readily available ot the skilled artisan, especially in light of the lack of predictability of the MLR assay for determining in vivo results. The ability to increase an in vitro graft versus host response may or may not be refelctive of an ability to stimulate an immune response in vivo (as indicated in the previous Office action).

With regard to the rejections of the claims under 102, the rejections are maintained in light of the lack of utility for the parent applications, and the denial of priority due to the lack of utility of the earlier applications.